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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,995	10/30/2003	Dorothea Reilly	11669.195USU1	7395

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MERCHANT & GOULD PC
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

EXAMINER	
CROWDER, CHUN	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/697,995	REILLY ET AL.	
	Examiner	Art Unit	
	Chun Crowder	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/20/2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-120* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-120* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

1. The instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

2. Applicant's Preliminary Amendment, filed 10/20/2004, is acknowledged.

Claims 5-8, 10-40, 42, 48-50, 52-55, 57, 58, 71, 74-77, 79-82, 84-88, 93-96, 103, 104, 108-110, 114-120 have been amended.

Claims 1-120 are pending.

3. It is noted that dependent claim 113 recites "the amount of claim 112...". For restriction purpose, claim 113 is read as "the method of claim 112...". Applicant is invited to clarify claim 113.

4. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-54 and 102, drawn to an antibody, immunoconjugate, a composition, and an article comprising a variant heavy chain hinge region incapable of inter-heavy chain disulfide linkage, classified in Class 530, subclasses 387.1 and 387.3; Class 424, subclass 130.1 and 134.1; Class 435, subclass 810.

II. Claims 55-101, 103-114, drawn to a polynucleotide encoding the antibody or immunocojugate, a vector, a host cells and a method of producing an antibody or Immunoadhesin, classified in Class 536, subclasses 23.4 and 23.54; Class 435, subclasses 71.2, 252.3, and 320.1.

III. Claims 115, 117-120, drawn to a method of treating, delaying or preventing a disease in a subject by administering an antibody or immunocojugate, classified in Class 424, subclasses 130.1 and 178.1.

IV. Claim 116, drawn to a method of diagnosing a disease in a subject by contacting the antibody or immunoconjugate to a tissue sample, classified in Class 435, subclass 7.1.

5. Groups I and II are different products. Antibody/immunoconjugate and polynucleotide are patentably distinct because their structures, physicochemical properties and/or mode of action are different, and they do not share a common structure that is disclosed to be essential for common utility. Further, they require non-coextensive searches in the scientific literature. Therefore, each product is patentably distinct, and searching of these inventions would impose undue burden.

6. Groups I and III/IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h).

In the instant case, the product antibody or immunoconjugate can be used for affinity purification in addition to methods of treating and diagnosing.

7. Groups III and IV are different methods. The methods differ with respect to one or more ingredients, method steps, and/or endpoints; therefore, each method is patentably distinct. Further, the distinct ingredients, method steps, and/or endpoints require separate and distinct searches. As such, it would be burdensome to search these invention together.

8. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

Species Election

9. This application contains claims directed to the following patentably distinct species of the claimed invention:

10. If either one of the Groups I-IV is elected, applicant is further required to elect one specific product of the followings:

A) an antibody with specific antibody subtype (e.g. IgG1 as recited in claim 17),

B) an aglycosylated antibody with specific antibody subtype (e.g. IgG1 as recited in claim 17), **OR**

C) an immunoconjugate with specific antibody subtype in the Fc region (e.g. IgG1 as recited in claim 17).

In addition, if applicant elect (A) or (B), then applicant must elect one specific antibody with one specific antigen binding capability (e.g. an antibody variant capable of binding to a tumor antigen as recited in claim 25) and to provide any functional limitation associated with the antibody (e.g. therapeutic antibody as recited in claim 19).

If applicant elect (C), then applicant must elect one immunoconjugate comprising one specific antibody conjugated with one specific heterologous moiety (e.g. calichemicin as recited in claim 45).

If applicant should acknowledge that these species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case.

These species are patentably distinct because their structures, physicochemical properties and/or mode of action are different, and they do not share a common structure that is disclosed to be essential for common utility. Further, the examination of these species would require different searches in the scientific literature. As such, it would be burdensome to search these species together.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

11. If Group II is elected, applicant is further required to elect one specific host cells comprising one specific prokaryotic polypeptide (e.g. DsbA as recited in claim 63, **AND** one specific method wherein:

A) the heavy and light chains of the antibody are encoded by a single polynucleotide, **OR**

B) the heavy and light chains are encoded by separate polynucleotides.

These species are patentably distinct because the methods differ with respect to one or more ingredients, method steps. Further, the examination of the different ingredients, method steps would require different searches in the scientific literature and electronic databases. As such, it would be burdensome to search these species together.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

12. If Group III is elected, applicant is further required to elect method of treating one specific disease (e.g. tumor as recited in claim 118).

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter. Further, the examination of species would require different searches in the scientific literature. As such, it would be burdensome to search these species together.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

It is noted that claims 180-120 contain recitations of "tumor", "cancer" or "immune disorder", while the specification discloses an extensive list of various diseases, at least on pages 26-27. In the event that an invention containing any of the above claims is elected, specific "diseases" are introduced into the claims during prosecution, additional species election will be required.

13. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

14. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. *Process claims that depend from or otherwise include all the limitations of the patentable product* will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. *Failure to do so may result in a loss of the right to rejoinder.*

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

15. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

16. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Crowder whose telephone number is (571) 272-8142. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chun Crowder, Ph.D.
Patent Examiner
March 5, 2006

PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
TC 1600
3/9/06